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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/638,693	08/15/2000	Geert Maertens	2752-15	2013

7590

09/11/2003

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EXAMINER

MARTINELL, JAMES

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/638,693

Applicant(s)

MAERTENS ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 56-91 is/are pending in the application.
- 4a) Of the above claim(s) 57,58,60-73,75 and 86-91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56,59,74 and 76-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6&20.                      6) ☐ Other:

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Applicant's election with traverse of the requirement for restriction in Paper No. 23 is acknowledged. The traversal is on the ground(s) that the examiner's assertion that the claimed invention is drawn to many thousands of polypeptides is unsubstantiated, that certain claims in the instant application correspond to claims in copending Serial No. 08/362,455, and that what corresponds to at least Group 2 in PCT/EP94/01323 ought to be examined in this application. In addition, applicants call attention to processing delays in the instant application. This is not found persuasive for the following reasons.

- (a) Applicants did not argue that the claimed polypeptides share a common special technical feature.
- (b) Applicant complains that the examiner merely asserts that the claims are drawn to many thousands of polypeptide. For the record, the claims recite many polypeptides of length greater than 100 amino acids each. There are 4656 possible 5-and-more-mers of any given 100-mer (*i.e.*, the sum of  $96 + 95 + 94 \dots 1$ ). Thus, without an exhaustive mathematical analysis, it is clear that the claims embrace and are drawn to many thousands of polypeptides that do not share a common special technical feature.
- (c) The prosecution of Serial No. 08/362,455 is not germane to the requirement for restriction in the instant application. The record in this application stands on its own.
- (d) No copy of the search Report for PCT/EP94/01323 is in the file as is asserted by applicants in paper no. 23.
- (e) The processing delays are regretted, but such delays cannot dictate any particular action regarding restriction of an application to only one invention. In addition, it is noted that applicants petitioned for a two month extension of time in order to respond to the requirement for restriction that was mailed on December 17, 2001.

The requirement is still deemed proper and is therefore made FINAL.

Claims 57, 58, 60-73, 75, and 86-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking

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claim. Applicant timely traversed the restriction (election) requirement in Paper No. 23. None of claims 57, 58, 60-73, 75, and 86-91 embraces an elected invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56, 59, 74, and 76-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, incomplete, inaccurate, and misdescriptive.

- (a) Claims 56, 59, 74, and 76-85 are vague and indefinite because they embrace more than the elected invention.
- (b) The recitation of "genotype-specific amino acid" (claim 56) is vague and indefinite because the instant application does not define the meaning of the term within the context of the claim.
- (c) Claim 74 is vague and indefinite because it is not known which embodiments contain the residues recited in the claim. For example, positions 1646-1764 is 119 residues and SEQ ID NO: 36 is 133 residues, yet claim 74 recites positions with values greater than 133. Thus, it is not understood to what the amino acid residues recited in the claim refer.
- (d) Claim 77 is incomplete because it is a process claim that recites no positive process step.
- (e) Claim 83 is inaccurate and misdescriptive in reciting "A kit . . . comprising the following steps" because this is a kit claim and a kit does not comprise steps.
- (f) The recitation of "possibly" (claims 82 and 83) is vague and indefinite. The term "optionally" is suggested as a replacement.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 56, 59, 74, and 76-85 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Simmonds et al (WO 93/10239 (27 May 1993)). Simmonds et al discloses peptides that are mentioned in the claims. For example, SEQ ID NO: 36, positions 64-77 matches positions 5-18 of the first sequence mentioned in claim 15 (page 90) of Simmonds et al and SEQ ID NO: 36, positions 79-97 matches the entire second sequence mentioned in claim 15 (page 90) of Simmonds et al. Simmonds et al further teaches the use of the polypeptides in the production of antibodies for use in antibody assays and also discloses the use of kits containing antibodies (*e.g.*, see pages 58-70 of Simmonds et al).

Claims 56, 59, 74, and 76-85 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Chien et al (U.S. 6,416,946). Chien et al discloses a polypeptide that is mentioned in the claims (*e.g.*, compare SEQ ID NO: 36, positions 26-31, 33-45, and 47-53 of the instant application with matches at positions 65-70, 72-84, and 86-92, respectively of SEQ ID NO: 1 of the reference. Antibody assays and kits are taught in Chien et al at columns 5-12.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

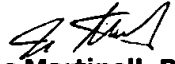
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028.

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**PLEASE NOTE THE NEW FAX NUMBER**

The fax phone number for the organization where this application or proceeding is assigned is  
(703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should  
be directed to the receptionist whose telephone number is (703) 308-0196.



**James Martinell, Ph.D.**  
**Primary Examiner**  
**Art Unit 1631**